PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Randomized, Subject and Evaluator Blinded, Sham Controlled, Multicenter Study to Evaluate Efficacy and Safety of NASHA/Dx for the Treatment of Fecal Incontinence

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study is to determine the effectiveness and safety of NASHA/Dx when used as an injectable bulking agent in the treatment of fecal incontinence. The study includes a 6-month blinded sham-controlled phase, followed by an open-label phase.

Brief Summary in Scientific Language

Subjects in the sham control group will have the option to receive open-label treatment with NASHA/Dx after the blinded phase.

Organizational Data

- DRKS-ID: **DRKS00004056**
- Date of Registration in DRKS: **2012/07/31**
- Date of Registration in Partner Registry or other Primary Registry: **2008/01/09**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00605826 (ClinicalTrials.gov)**
- Sponsor-ID: **33DA0404 (Q-Med Scandinavia, Inc.)**

Health condition or Problem studied

- Free text: **Fecal Incontinence**
- ICD10: **R15 - Faecal incontinence**

Interventions/Observational Groups

- Arm 1: **Device: NASHA/Dx Injectable Gel**
- Arm 2: **Device: Sham Injection**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Proportion of subjects who are Responder50.; time frame: 6 months after last blinded treatment; Proportion of subjects who achieve ≥ 50% reduction in the number of fecal incontinence episodes compared to baseline (Responder50).
- Proportion of subjects who are Responder25.; time frame: 12 months after last blinded treatment; Proportion of subjects who achieve ≥ 25% reduction in the number of fecal incontinence episodes compared to baseline (Responder25).

Secondary Outcome

- Number of fecal incontinence episodes; time frame: upto 36 months after last treatment
- Number of incontinence free days; time frame: upto 36 months after last treatment

- Fecal Incontinence Quality of Life Scale (FIQL).; time frame: upto 36 months after last treatment; Fecal Incontinence Quality of Life Scale (FIQL).
- Cleveland Clinic Florida Incontinence Score (CCFIS).; time frame: upto 36 months after last treatment; Cleveland Clinic Florida Incontinence Score (CCFIS).
- Adverse Events; time frame: 6 months after last blinded treatment and upto 36 months after last treatmtent; Adverse events reported during the 6 month blinded phase of the study.

Countries of recruitment

- US **United States**
- DE **Germany**
- SE **Sweden**
- UK **United Kingdom**

Locations of Recruitment

- **Chirurgische Klinik Mit Poliklinik, FAU Erlangen-Nurnberg, Erlangen**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2006/08/31**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- 18-75 years of age, male or female

- Screening fecal incontinence severity score (CCFIS)

- Fecal incontinence episodes over a 14-day period

- Failed conservative treatment for fecal incontinence

Exclusion criteria

- Complete external sphincter disruption

- Significant anorectal disease

- Anorectal surgery within the last 12 months prior to the study

- Active Inflammatory Bowel Disease (IBD)

- Immunodeficiency or receiving immunosuppressive therapy

- Malignancies in remission for less than 2 years prior to the study

- Bleeding disorders or receiving anticoagulant therapy

- Chemotherapy within the last 12 months prior to the study

- Prior Pelvic radiotherapy

- Women who are pregnant or breast-feeding, or women of childbearing potential not practicing adequate contraception or planning to stop such contraception within the first year of the study

- Women within one year post partum

- Participation in any other clinical study within 3 month prior to the study

- Hypersensitivity to hyaluronic acid containing products

- Other severe conditions or in other ways unsuitable to participate according to investigator judgement

Addresses

■ **Primary Sponsor**

Q-Med Scandinavia, Inc.

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

■ **[---]***

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Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 5
- Last processed date by ClinicalTrials.gov: 2016/01/14
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.